K01 3293

NIPRO MEDICAL CORPORATION
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DEC 1 4 2001

SUMMARY OF SAFETY AND EFFECTIVENESS FOR NIPRO HYPODERMIC NEEDLE

§807.92 (a)(1)

Hypodermic Single Lumen Needle
21CFR 880.5570

Contact Person: Eiji Shinozaki

Date of Summary Preparation: December 14, 2001

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: K944355 Nipro Hypodermic Needle

§807.92 (a)(4)

Description of the Device:
The devices that we intend to market are hypodermic needles as described in 21 CFR §880.5570. Two types of hypodermic needles will be available: types L (long) and S (short). Type L hypodermic needles are 1¼ to 1½ inches long and Type S needles ¾ to 1 inch long.

§807.92 (a)(5)

Intended Use:
The Nipro® Hypodermic Needle is intended to be used to inject fluids into or withdraw fluids from parts of the body below the surface of the skin.

§807.92 (a)(6)

Comparison of Technical Characteristics:
Nipro Hypodermic Needles are similar in design, technical, performance, and biological characteristics to those marketed under K944355.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2001

Ms. Kaelyn B. Hadley
Consultant
Nipro Medical Corporation
1384 Copperfield Court
Lexington, Kentucky 40514

Re: K013293
Trade/Device Name: Nipro® Hypodermic Needle
Regulation Number: 880.5570
Regulation Name: Hypodermic Needle
Regulatory Class: II
Product Code: FMI
Dated: September 27, 2001
Received: October 2, 2001

Dear Ms. Hadley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) number (if known): K013293

Device name: Nipro® Hypodermic Needl

Indications for use: The Nipro® Hypode mic Needle is intended to be used to inject fluids into or withdraw fluids from parts of the body be ow the surface of the skin.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013293

(Do not write below this line- continue c n another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The- Counter-Use___ (optional Format 1-2-9)